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The Commonwealth of Massachusetts
Executive Office of Health and Human Services
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Bureau of Environmental Health
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June 28, 2010

Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Markey;

This letter is in response to your letter dated March 18, 2010 requesting information regarding Massachusetts's regulation of patients being treated and released with medical isotopes including iodine-131 (I-131). Please note that the Commonwealth of Massachusetts's Regulations for the Control of Radiation can be found on the Massachusetts Department of Public Health's (MDPH) website at www.mass.gov/dph/rcp. With respect to the issue of medical treatments involving I-131, we have worked with both the provider community and the public to better address these concerns as discussed later in Attachment 1 of this correspondence.

The Massachusetts Department of Public Health is designated by statute [M.G.L. Chapter 111: Section 5N] as the state radiation control agency. Oversight of the regulation of radioactive materials licensees and registrants, users of x-ray devices, radon, and low-level radioactive waste is performed by the Radiation Control Program, which is part of the MDPH Bureau of Environmental Health.

We have provided information in response to the questions you raised in your letter (Attachment 1). Attachment 2 contains a copy of the field note form we use for inspections of medical facilities licensed to use radioactive materials. If you need additional information or need further clarification, please do not hesitate to contact Suzanne Condon, Associate Commissioner, at 617-624-5757 or me at 617-242-3035 ext. 2001.

Sincerely,

Robert L. Gallaghar, Acting Director

cc: Suzanne K. Condon, Associate Commissioner/Director, Bureau of Environmental Health
Dan Delaney, Legislative Director, MDPH

Enclosures

Attachment 1

Question 1:

How many iodine-131 (I-131) facilities are overseen by your State?

Response 1:

We have 54 licensees that are authorized to use iodine-131 in therapeutic quantities (i.e. quantities that exceed 30 microcuries, which require a written directive).

Question 2:

How often does your State perform sampling inspections at each of these I-131 licensee facilities?

Response 2:

In Massachusetts we inspect medical licensees authorized to administer therapeutic quantities of I-131 every one to three years, depending on the type and scope of the program. For example, complex medical institutions of broad scope with multiple locations of use (Massachusetts General Hospital is a good example) are inspected annually (the NRC frequency is every 2 years); medical institutions with specific licenses that administer therapeutic doses of I-131, referred to as Medical Institution – Written Directive Required, require an inspection every 3 years.

Question 3:

What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 3:

Massachusetts follows all NRC applicable guidance outlined in Inspection Manual Chapter 2800 (IMC 2800) which includes the inspection criteria for a licensee requiring written directives for the administration of I-131 and is contained in NRC Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required." We have developed our own inspection procedure which is based on IP 87131 (see Attachment 2 to this letter). This procedure requires, in part, the inspector determine by direct observations and, if needed, review of selected records that the licensee is knowledgeable about patient release criteria and is in compliance with the patient release criteria in 105 CMR 120.500. Inspectors review a representative sample of the licensee's written instructions to the patient to determine if the instructions meet current requirements.

Question 4:

NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients."[4] For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 4:

Enclosed, please find a copy of our brochure developed by the Bureau of Environmental Health in response to public health concerns about exposure to family members from patients treated with radiopharmaceuticals. The brochure answers frequently asked questions and provides recommendations to reduce the risk of exposure to children or infants at home. The brochure is available to the public on our website: http://www.mass.gov/dph/rcp under Radiation Control Topics, Radioactive Materials, Advisories and Policies.

The guidance provided to medical use licensees contained in AGENCY INFORMATION NOTICE 09-02 "RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS" (Attached as Appendix 3) states "the Agency discourages physicians from suggesting patients use hotels as a means of separating them from infants or young children, since that practice has proven to cause significant contamination of hotel property and raises concerns on the issue of exposures to housekeeping staff and guests."[1]

Question 5:

In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

Response 5:

During every inspection of I-131 therapy programs at medical use facilities using quantities that require a determination of whether to release the patient under 105 CMR 120.500, our inspectors evaluate the licensee's patient release program to verify compliance with the Massachusetts Regulations for the Control of Radiation (MRCR). This includes determining if the licensee is knowledgeable about release criteria; maintains appropriate records to document the basis for authorizing the

[1] Agency means the Massachusetts Department of Public Health Radiation Control Program.

individual's release; and provides adequate instructions to patients. Additional documentation is requested and/or additional interviews of licensee personnel are conducted during the inspection if deficiencies are noted. This is standard procedure for each inspection of medical use licensees having authorization for radiopharmaceutical therapy with iodine-131. In addition, as mentioned in the response to question #4, we distributed Agency Information Notice 09-02, (Release of Patients Treated with Radiopharmaceuticals" to all medical licensees.

Question 6:

In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensed care?

Response 6:

When the patient release rule was promulgated by the NRC, the Agency required all medical licensees to submit a request to allow the release of patients treated with I-131 and include copies of the instructions to be provided to each patient. This information was reviewed by our license reviewers and approved in accordance with standard licensing review procedures. During routine inspections, our inspectors review a representative sampling of these instructions for compliance with the regulations and the commitments tied to each license. Copies of documentation reviewed as part of routine inspections are not retained as part of the inspection record.

Question 7:

In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 7:

In the past ten years Massachusetts inspectors have not identified any specific problems with the individualized analyses or dose calculations performed by any of our licensees or in guidance provided to the patients.

Question 8:

In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8:

It was due to these concerns that we developed our brochure/guidance "Protecting Children and Infants from Exposure to Radiopharmaceuticals Associated with Patient Care." The guidance provided to medical use licensees contained in AGENCY INFORMATION NOTICE 09-02 "RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS" (Attached as Appendix 3) states "the Agency discourages physicians from suggesting patients use hotels as a means of separating them from infants or young children, since that practice has proven to cause significant contamination of hotel property and raises concerns on the issue of exposures to housekeeping staff and guests."

Question 9:

Has your State ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

Response 9:

Release of patients treated with radiopharmaceuticals is reviewed during each inspection of medical licensees by interviews with licensee staff as well as a review of records. The standard practice of our inspectors is to verify compliance with the applicable regulations for patient release but does not include making note of the number of individuals treated following radioiodine therapy and released or held in the hospital for several days.

The Agency did receive an allegation (made by a friend of a patient) in 2003 involving a patient having been advised to go to a hotel for a few days after treatment. The Agency performed a thorough investigation of this allegation and was not able to find any evidence that any patients did in fact go to a hotel following treatment. The policy of the hospital involved states "under no circumstances should an individual undergoing this type (*radioiodine*) of therapy use hotels, motels, or any public accommodations." A copy of our investigation and related materials is attached as Attachment 4. Limited resources have not allowed for conducting a survey of patients regarding their activities immediately following treatment/release.

Question 10:

In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Response 10:

As discussed in previous responses, Massachusetts inspectors evaluate the licensee's program for patient release to verify compliance with existing Massachusetts regulations. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. We have not found any situations where the dose calculations were not performed, but unfortunately lack the resources to more effectively explore this to provide a more comprehensive response to your question.

Question 11:

What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

Response 11:

Massachusetts does not have any such disclosure rules for patients to give to hotels. Instead, we recommend that licensees refer to the guidance provided in AGENCY INFORMATION NOTICE 09-02 "RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS" (Attached as Appendix 3), which states "the Agency discourages physicians from suggesting patients use hotels as a means of separating them from infants or young children, since that practice has proven to cause significant contamination of hotel property and raises concerns on the issue of exposures to housekeeping staff and guests." In addition, as mentioned previously, the Bureau of Environmental Health developed a brochure, which is posted on the MDPH website, to be distributed to patients.

Question 12:

Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.

Response 12:

Yes. DPH issued AGENCY INFORMATION NOTICE 09-02 "RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS" in August of 2009 (Attached as Appendix 3) and created the patient brochure which is on our website and has been distributed to a variety of parties.

Question 13:

Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?

Response 13:

Massachusetts laws do not require such a report. Once a patient is released under 105 CMR 120.500, there are no further requirements for either the patient or the licensee.

Question 14:

Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radio-nuclides.

Response 14:

The only correspondence we have is the routine review of our program through the Integrated Materials Performance Evaluation Program (IMPEP). These reports may be found on the NRC's website: http://nrc-stp.ornl.gov/reviews.html#MA.

Question 15:

Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Response 15:

If documents required to be maintained for inspection under 105 CMR 120.500 were found to be missing or incomplete it would be considered a violation of Massachusetts regulations and would be cited as such by the Agency. If documentation reviewed during an inspection was determined to be unclear, the inspector typically asks additional questions to determine whether or not a violation has occurred. There are no known cases where patients went to a hotel following radioiodine treatment in Massachusetts.

STATE OF MASSACHUSETTS

NUCLEAR MEDICINE INSPECTION FIELD NOTES

NOTE: All areas indicated in field notes are not required to be addressed during each inspection

NOTE: Any reference to patient is intended to include human research subject

Inspection Report No: _____ License No: _____

Licensee (Name & Address): Docket No: _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No: _____

Last Amendment No: _____ Date of Amendment _____

Priority ____
Program Code _____

Date of Last Inspection _____
Date of This Inspection _____

Type of Inspection:
( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations
( ) Violation(s)
( ) Violation(s), State letter issued
( ) Follow up on Previous Violations

Were non-cited violations identified during this inspection? ( ) Y ( ) N

Was proprietary information reviewed by or received by the inspector? ( ) Y ( ) N

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

B. Licensee does limited distribution of pharmaceuticals under 120.128(J) license[1] ( )Y ( )N

1. Indicate type of operation: [120.128(J)(1-4))]

___ a. Registered or licensed with FDA as a drug manufacturer
___ b. Licensed as a pharmacy by State Board of Pharmacy

2. Licensee distributes

* sealed sources ( )Y ( )N
* alpha and beta emitters ( )Y ( )N
* generators ( )Y ( )N
* photon emitters ( )Y ( )N

Remarks:

C. Research involving human subjects ( )N/A

2. Research is conducted, funded, supported, or regulated by a Federal Agency which has implemented Federal Policy for Protection of Human Subjects[2]? [120.503(C)] ( )Y ( )N

If no, does licensee have license amendment authorizing human research? ( )Y ( )N

2. Licensee obtains informed consent from human subjects? [120.503(C)] ( )Y ( )N

3. Licensee obtains approval of research activities from an Institutional Review Board? [120.503(C)] ( )Y ( )N

Remarks:

D. Radiation Safety Committee ( )N/A

1. Membership as specified [120.508(A)(1)] ( )Y ( )N
2. Meetings held quarterly [20.508(A)(2)] ( )Y ( )N
3. Quorums established [120.508(A)(3)] ( )Y ( )N
4. Record maintained [120.508(A)(4)] ( )Y ( )N
5. Approve/disapprove credentials of individuals prior to allowing them to work as an authorized user or authorized nuclear pharmacist [120.508(B)(2)] ( )Y ( )N
6. Has sufficient authority [120.509] ( )Y ( )N

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[1]If licensee distributes radiopharmaceuticals to several facilities, the inspector should consider the need to complete the radiopharmacy field notes.

[2]Agencies: USDA, DOE, NASA, HUD, DOJ, DOD, VA, EPA, HHS, DOT, Dept. of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency, Agency for International Development, Dept. of Education, National Science Foundation

2. Licensee has notified Agency within 30 days after authorized user or nuclear pharmacist or RSO stops work or changes name or licensee's mailing address changes [120.505] ( )N/A ( )Y ( )N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers [120.753] ( )Y ( )N
B. Individual's understanding of current procedures and regulations is adequate ( )Y ( )N
C. Training program required [L/C] ( )Y ( )N

1. If so, briefly describe training program:
2. Training program implemented ( )Y ( )N
3. Periodic training program required ( )Y ( )N
4. Periodic training program implemented ( )Y ( )N
5. Records maintained ( )Y ( )N

D. Supervision of individuals by authorized user in accordance with [120.510] ( )Y ( )N

1. Supervised individuals[3] are instructed in preparation of material, principles and procedures for radiation safety and QM Program as appropriate [120.510(A)(1),510(B)] ( )Y ( )N

2. Licensee periodically reviews supervised individuals use of material and records kept to reflect use [120.510(A)(2)] ( )Y ( )N

3. Authorized nuclear pharmacist or user periodically reviews work and records of work of supervised individuals as it pertains to preparing byproduct material [120.510(C) ( )N/A ( )Y ( )N

Remarks:

E. Therapy training ( )N/A

1. Safety instruction [120.538, 544, L/C]

a. Control of patient and visitors ( )Y ( )N
b. Contamination and waste ( )Y ( )N
c. Size/appearance of sources ( )N/A ( )Y ( )N
d. Handling/shielding of sources ( )N/A ( )Y ( )N
e. RSO notification in emergency or death ( )Y ( )N
f. Records maintained [120.538(C), 544(C)] ( )Y ( )N

[3]Applies to individuals that receive, possess, use, transfer, or prepare byproduct material for medical use under supervision of authorized nuclear pharmacist or user.

2. Constancy [120.517(B)(1)]

   a. Performed daily ( )Y ( )N
   b. Dedicated check source used ( )Y ( )N

3. Accuracy [120.517(B)(2)]

   a. Performed at installation and annually ( )Y ( )N
   b. At least 2 sealed sources used ( )Y ( )N

4. Linearity [120.517(B)(3)]

   a. Performed at installation and quarterly thereafter ( )Y ( )N
   b. Includes range between 10 uCi and the highest dosage administered ( )Y ( )N

5. Geometry Dependence [120.517(B)(4)]

   a. Performed at installation or relocation ( )Y ( )N
   b. Includes range of volumes and volume configurations used ( )Y ( )N

6. Dosage readings mathematically corrected for geometry or linearity errors greater than ±10% [120.517(C)] ( )N/A ( )Y ( )N

7. Repaired or replaced when constancy or accuracy errors exceeded ±10% [120.517(C)] ( )N/A ( )Y ( )N

8. Approved procedures followed [120.507, L/C] ( )Y ( )N

9. Records maintained and include identity of the individual performing the test. [120.517(E)(2),(3),(4)] ( )Y ( )N

Remarks:

B. Instrumentation - Alpha- or beta-emitting radionuclides ( )N/A

1. List type of equipment used to assay alpha and beta particles:

2. Licensee has procedures for use of instrumentation [120.517(A)] ( )Y ( )N

If yes,

1. Licensee receives unit dosages and relies on assay data supplied by manufacturer or properly licensed organization [120.519(B)] ( )Y( )N
2. Licensee measures by direct measurement or combination of measurement and calculation each dosage of alpha or beta-emitting radionuclide prior to medical use[120.519(B),L/C] ( )Y( )N

C. Unsealed material used under 120.531(B), 533(B), or 537(B) are:

1. Obtained from manufacturer or properly licensed organization; AND/OR ( )Y( )N

2. Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of a authorized nuclear pharmacist or physician user [120.568] ( )Y( )N

Remarks:

D. Isotope, chemical form, quantity and use as authorized [120.122(I), 120.541,543, L/C] ( )Y( )N

Remarks:

E. Use of radiopharmaceuticals [L/C]

1. Protective clothing worn ( )Y( )N
2. Personnel routinely monitor their hands ( )Y( )N
3. No eating/drinking in use/storage areas ( )Y( )N
4. No food, drink, or personal effects kept in use/storage areas ( )Y( )N
5. Proper dosimetry worn ( )Y( )N
6. Radwaste disposed in proper receptacles ( )Y( )N

F. Leak tests and Inventories

1. Leak test performed on sealed sources and brachytherapy sources [120.521(B)] ( )Y( )N
2. Inventory of sealed sources and brachytherapy sources performed quarterly [120.521(G)] ( )Y( )N
3. Inventory performed promptly at the storage area after removing sources from a patient and includes required information [120.546(A)] ( )Y( )N
4. Records maintained & signed [120.521(D) 120.546] ( )Y( )N

Remarks:

8. RADIOPHARMACEUTICAL THERAPY ( ) N/A

A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release and contamination controls [120.539(A)(B), L/C] ( ) Y ( ) N

B. Area dose rate surveys and room contamination surveys [120.539(A)(4)(7)] ( ) Y ( ) N

C. Release of patients containing radiopharmaceuticals meets <5 mR/hr @ 1m or < 30 mCi [120.527(A)(1),(2)] ( ) Y ( ) N

D. RSO promptly notified if patient died or had a medical emergency [120.539(C)] ( ) N/A ( ) Y ( ) N

Remarks:

9. BRACHYTHERAPY ( ) N/A

A. Safety precautions implemented to include patient facilities, posting, stay times, and area radiation level surveys [120.545, L/C] ( ) Y ( ) N

B. Patients surveyed immediately after implant [120.546(C)] ( ) Y ( ) N

C. Release of patients with permanent implants meets 5 mR/hr @ 1m [120.527(A)] ( ) N/A ( ) Y ( ) N

D. Patients surveyed immediately after removing the last temporary implant source (required for all manual, LDR, MDR, and HDR therapies) [120.546(C)] ( ) N/A ( ) Y ( ) N

E. Records maintained [120.545(A)(4), 546(D), 547(B)] ( ) Y ( ) N

Remarks:

10. RADIOACTIVE WASTE ( ) N/A

A. Disposal

1. Decay-in-storage ( ) N/A

a. Approved [120.251, 120.530, L/C] ( ) Y ( ) N
b. Procedures followed [L/C] ( ) Y ( ) N
c. Labels removed or defaced [120.244, 530] ( ) Y ( ) N

2. Special procedures performed as required [L/C] ( ) Y ( ) N
3. Improper/unauthorized disposals [120.251] ( ) Y ( ) N
4. Records maintained [120.263(A), 269, L/C] ( ) Y ( ) N

Remarks:

C. Waste storage

1. Protection from elements and fire [L/C] ( )Y( )N
2. Control of waste maintained [120.235] ( )Y( )N
3. Containers properly labeled and area properly posted [120.242, 244] ( )Y( )N
4. Package integrity adequately maintained [L/C] ( )Y( )N

D. Records of surveys and material accountability are maintained [120.263, 269] ( )Y( )N

Remarks:

11. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL ( )N/A

A. Describe how packages are received and by whom:

B. Written package opening procedures established and followed [120.246(E)] ( )Y( )N
C. All incoming packages with a DOT label wiped, unless exempted (gases and special form) [120.246(B)(1)] ( )Y( )N
D. Incoming packages surveyed [120.246(B)(2), L/C] ( )Y( )N
E. Monitoring in (C) and (D) performed within time specified [120.246(C)] ( )Y( )N
F. Transfer(s) between licensees performed per [120.140] ( )Y( )N
G. All sources surveyed before shipment and transfer [120.225(A), 49 CFR 173.475(i), L/C] ( )Y( )N
H. Records of surveys and receipt/transfer maintained [120.263(A), 120.009] ( )Y( )N
I. Package receipt/distribution activities evaluated for compliance with 120.221 [120.222] ( )Y( )N

Remarks:

12. TRANSPORTATION (120.775(A) and 49 CFR 171-189) ( )N/A

A. Licensee shipments are:

( ) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

B. Licensee returns radiopharmacy doses ( )N/A ( )Y( )N

1. Licensee assumes shipping responsibility ( )Y( )N
2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

3. Aerosols and gases sampled [120.535] ( )Y( )N
4. Monitoring/controlling program implemented (includes bioassays) [120.539(A)(B), 535(E), L/C] ( )Y( )N
5. Respiratory protection equipment [120.233] ( )Y( )N

Remarks:

E. Reports

1. Reviewed by _____ Frequency _____
2. Inspector reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [120.205] ( )Y( )N
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organs _____
6. Maximum CEDE _____
7. Licensee sums internal and external [120.212] ( )Y( )N
8. TEDEs and TODEs within limits [120.211] ( )Y( )N
9. Agency forms or equivalent [120.215(D), 267(C)]

a.	120.200-2	( )Y( )N	Complete:	( )Y( )N
b.	120.200-3	( )Y( )N	Complete:	( )Y( )N

10. Worker declared her pregnancy in writing during inspection period (review records) ( )N/A( )Y( )N
If yes, licensee in compliance with [120.218] ( )Y( )N
and records maintained [120.267(D)] ( )Y( )N

F. Who performed any PSEs at this facility (number of people involved and doses received) [120.216, 215, 266, 284] ( )N/A

G. Records of exposures, surveys, monitoring, and evaluations maintained [120.262, 263, 267, 535(G), 539(A)(8), L/C] ( )Y( )N

Remarks:

14. MISADMINISTRATIONS AND RECORDABLE EVENTS ( )N/A

A. If misadministrations or recordable events (misadministration defined in 120.502) have occurred since the last inspection, evaluate the incident(s) and the licensee's quality management program (QMP) using the existing guidance. [120.514]

1. Event date _____Information Source _____
2. Notifications

State (24 hours)	( )Y( )N	Patient (24hrs)	( )Y( )N
Referring Phys.(24 hrs)	( )Y( )N	In writing	( )Y( )N

18. RECORDKEEPING FOR DECOMMISSIONING ( ) N/A

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [120.125(C)(1)(h)] ( ) Y ( ) N

B. Records include all information outlined in [120.125(C)(1)(h)] ( ) Y ( ) N

Remarks:

19. SPECIAL LICENSE CONDITIONS OR ISSUES ( ) N/A

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Remarks:

20. MEDICARE SERVICES INSPECTION: (Title 42, Public Health; Chapter IV; Part 482.53; Conditions of Participation For Hospitals, Nuclear Medicine Services)
Note: Only required for those facilities that provide medicare services

A. Organization and staffing

1. Nuclear medicine department staff includes a a director who is a doctor of medicine or osteopathy qualified in nuclear medicine [482.53(a)(1)] ( ) Y ( ) N
2. Qualifications, training, functions, and responsibilities of nuclear medicine personnel are identified by policy and procedure and approved by the medical staff [482.53(a)(2)] ( ) Y ( ) N

B. Delivery of Service

1. Facility prepares and distributes radiopharmaceuticals as a nuclear pharmacy [120.128(J)] ( ) N/A ( ) Y ( ) N
   a. In-house preparation of radiopharmaceuticals by or under the direct supervision of a qualified nuclear pharmacist [120.580, 120.581, 482.53(b)(1)] ( ) Y ( ) N
2. In-house preparation of radiopharmaceuticals by or under the direct supervision of a doctor of medicine or osteopathy [482.53(b)(1)] ( ) Y ( ) N

22. DEBRIEF WITH LICENSING STAFF

Inspection findings discussed with licensing staff ( ) N/A ( ) Y ( ) N

Items discussed:

23. VIOLATIONS, NCVs, AND OTHER ISSUES

Note: Briefly state (1) the requirement and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited.

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Radiation Control Program
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August 25, 2009

AGENCY INFORMATION NOTICE 09-02

RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS

Addressees

All medical use licensees authorized to administer radiopharmaceuticals to patients or human research subjects.

Purpose

The Massachusetts Radiation Control Program (Agency) is issuing this information notice to provide guidance to medical licensees who need to meet the regulatory requirements as specified in 105 CMR 120.540 relating to the release of patients containing unsealed radioactive material.

While no written response is required, it is expected that recipients will review the information for applicability to their activities and consider implementing appropriate actions that may be needed.

Background

Issue 1 - Radiation and contamination exposure to infants and children.

In May 2008, the US Nuclear Regulatory Commission (NRC) issued *Regulatory Issues Summary* (RIS) *2008-11, Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration Of Iodine-131*. A copy of the pertinent text from this document is attached as Appendix 1. The RIS describes a recent finding by the International Commission on Radiological Protection that the internal dose to the thyroid for infants and young children who may come in contact with a patient recently administered therapeutic quantities of I-131, such as oral sodium iodide I-131, could be significant. NRC's guidance for medical institutions on patient instructions recommends, among other things, that medical institutions not release patients if there is a risk that infants or children would be exposed should the patient go home.

Issue 2 - Detection of contaminated items in household trash

Many solid waste management facilities in Massachusetts and elsewhere, such as landfills and transfer stations, are performing radiation surveys on arriving vehicles hauling household trash. As a result, the Agency is receiving an unacceptably large number of legally-required notifications of the detection of radioactive materials in these loads. Each instance of detection is investigated by the Agency and the involved city/town or waste hauler to identify the radioactive material causing the alarm and to ensure that it is controlled and disposed of properly. The large number of these events (around 120 each year) has resulted in significant resource impacts to all parties involved.

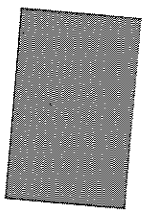
These investigations usually include dismantling the trash load and opening, examining and sampling the contents of the trash bags which contain the radioactive material, potentially exposing investigators to conventional and biological hazards that are in addition to any radiological hazards. Most of these occurrences turn out to be due to excreted medical radioisotope contamination on items discarded by nuclear medicine patients in their household trash. In many cases, the individual patient may be identified by other items found in the trash bag, such as discarded mail. When this occurs, Agency inspectors typically visit the household to counsel the patient or his/her family against discarding radiologically contaminated material in household trash. Some municipalities and transfer stations are considering passing on the costs associated with these investigations and cleanups to the responsible party.

In a recent case, a large tractor trailer truck belonging to a Massachusetts municipality carrying 28 tons of trash was turned away from a solid waste handling facility when radiation was detected in the load. The radioactive material was located near the front of the trailer, and almost the entire 28 tons of trash had to be dumped out at the town facility and searched by Agency and town employees. Eventually, a trash bag containing a dozen or so radioactive adult diapers was found and segregated.

Action Requested

Issue 1 - Recommendations for reducing exposures to infants and children

Please review your written and oral patient release instructions to ensure they contain appropriate precautions regarding exposure to infants and children from radiation and contamination. Consideration should be given to extending a patient's stay if acceptable alternatives are not available to avoid contact with infants and children following therapeutic administration of radiopharmaceuticals. There are documented cases from other states regarding medical institutions recommending that patients check into a hotel for a period of time to avoid contact with children; the Agency discourages physicians from suggesting patients use hotels as a means of separating them from infants or young children, since that practice has proven to cause significant contamination of hotel property and raises concerns on the issue of exposures to housekeeping staff and guests.



Issue 2 - Clarifications on waste disposal by patients administered radiopharmaceuticals

Please ensure that your written and oral patient release instructions contain a section cautioning the patient against discarding any potentially contaminated excreta into their household trash. Disposal through the sanitary sewer should be emphasized as the appropriate alternative, because excreta from patients undergoing medical diagnosis or therapy is expressly exempted from the limitations on sewer disposal found in 105 CMR 120.253(A). Instructing the patient to bag and store waste items that cannot be flushed to the sewer would also be an acceptable alternative to disposal in regular trash, provided that the patient is given an estimate of when the material will have decayed so that it can be treated as regular trash. In addition to minimizing public dose and investigation costs, it would also help protect the privacy of a patient, which is frequently compromised during a search of his or her trash. It would also minimize the unnecessary exposure to investigators from other hazardous materials, and would minimize the possibility that an individual patient or a medical facility might be invoiced by a waste management facility for their cost of the investigation.

Sincerely,

Robert Walker

Robert Walker, Director
Radiation Control Program

Encl (1)

APPENDIX 1

Excerpt of Pertinent Information From NRC Regulatory Issue Summary 2008-11

PRECAUTIONS TO PROTECT CHILDREN WHO MAY COME IN CONTACT WITH PATIENTS RELEASED AFTER THERAPEUTIC ADMINISTRATION OF IODINE-131

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

NRC is issuing this regulatory issue summary (RIS) to inform licensees of supplemental guidance to NUREG 1556, Volume 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses" on the precautions that should be taken to protect infants and young children who may come in contact with patients released after administration of therapeutic amounts of iodine-131 (I-131), such as oral sodium iodide I-131. No specific action or written response is required. NRC is providing this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate.

BACKGROUND

On January 29, 1997, NRC published a final rule in the *Federal Register* on the "Criteria for the Release of Individuals Administered Radioactive Material" (62 FR 4120). This rule amended the patient release criteria in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," replacing the activity-based or dose-rate-based release limit with a limit based on projected radiation doses to other individuals exposed to a patient released after therapeutic administration of radionuclide, such as oral sodium iodide I-131. These dose-based release limits used assumptions that the internal doses for individuals who may come in contact with released patients were very small compared with doses from external exposures. Also, these criteria were consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) at the time.

However, in ICRP Publication 94 "Release of Patients after Therapy with Unsealed Radionuclides," published in 2004, ICRP cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," which states

that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

SUMMARY OF ISSUE

The regulations in 10 CFR 35.75 permit a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)." However, as described in the Background section of this RIS, for some I-131 therapies, such as oral administration of sodium iodide I-131, the ICRP cautions that the internal dose to infants and young children who may come in contact with a released patient could be significant.

NRC has developed guidance on recommended instructions that licensees should give I-131 therapy patients who are about to be released from licensee control and who will or may have contact with infants and young children. The guidance recommends that licensees consider not releasing patients, administered I-131, whose living conditions may result in unnecessary exposure of infants and young children.

The guidance mentioned above may be found in Enclosure 1 of this RIS and at the NRC's Web page entitled "Medical Uses Licensee Toolkit" at ttp://www.nrc.gov/materials/miau/med-usetoolkit.html. Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses."

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/
Robert J. Lewis, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Duane White, FSME
(301)415-6272
E-mail: dew2@nrc.gov

Enclosures:

1. Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131

Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131

The Nuclear Regulatory Commission (NRC) regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)." For this guidance document, the individual or human research subject to whom the radioactive material has been administered is called the "patient." Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses."

NRC's current patient release criteria were based, in part, on the assumption that internal doses to an individual from a patient released after therapeutic administration of a radionuclide, such as oral sodium iodide I-131, was small compared with doses from external exposures.

However, in 2004, the International Commission on Radiation Protection (ICRP), in ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides," cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," which states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

Section 35.75(b) of 10 CFR Part 35 requires the licensee to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In consideration of the more recent ICRP recommendations described above, the licensee, in implementing the requirements on written instructions in 10 CFR 35.75(b), should take into account whether the released patient may come in contact with infants or young children. In such a situation, in order to protect infants and young children from possible I-131 contamination, the licensee should provide the patient with additional instructions. These additional instructions should include:

- A recommendation to have patients avoid direct or indirect contact (e.g., indirect contact includes contamination from shared living space) with infants and young children for a specific period of time (e.g., consider having children stay outside the home with other family members).
- A recommendation for patients to have adequate living space at home (e.g., bedroom, bathroom) that can be used exclusively by the patient for a specific period of time.

- Information on the potential consequences, if any, from failure to follow these recommendations.

Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children

Why is proper disposal of such waste important?

Improper disposal of radioactive material can be detected at solid waste facilities. When detected, it requires considerable resources from the MPDH/RCP, local waste management officials and trucking company staff to isolate and identify what the radioactive material is so it can be properly managed. In FY09, MDPH/RCP responded to 120 incidents involving radioactive materials at waste facilities across the Commonwealth. Virtually all of these were caused by the improper disposal of personal items contaminated by radiopharmaceuticals. Of equal significance is the fact that the detailed trash inspection process often reveals items (e.g., envelopes with the name and address of the patient) which compromise the privacy of a patient whenever there is a report of the discovery of radioactive material in a trash load.

For More Information

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Bureau of Environmental Health
Massachusetts Department of Public Health
Schrafft's Center, Suite 1M2A
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Bureau of Environmental Health
MA Department of Public Health
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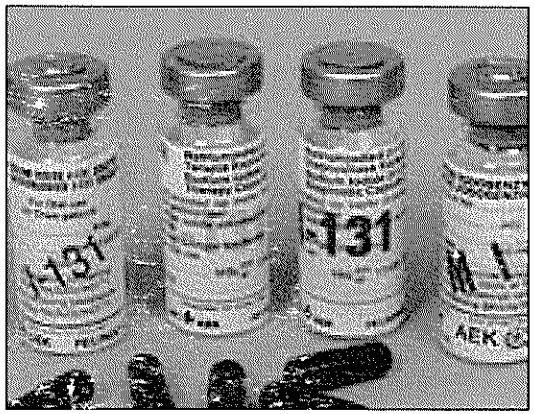
TTY: 617-624-5286

www.mass.gov/dph/environmental_health

August 2009

Protecting Children and Infants from Exposure to Radiopharmaceuticals Associated with Patient Care



Massachusetts Department of Public Health
Bureau of Environmental Health
Radiation Control Program
in collaboration with the
Environmental Health Education and Outreach Program

What are radiopharmaceuticals?

Radiopharmaceuticals are radioactive compounds used in a wide range of medical treatments that are meant to improve the health of individuals. One of the more common radiopharmaceuticals in use today contains radioactive iodine-131, or "I-131".

What are the concerns about exposure to children resulting from contact with patients treated with radiopharmaceuticals?

The International Commission on Radiological Protection recently reported that the internal dose to the thyroid for infants and young children who may come in contact with a patient recently administered therapeutic quantities of I-131, such as oral sodium iodide I-131, could result in significant doses to the child's thyroid and potentially raise the risk of subsequent radiation-induced thyroid cancer.

What is MDPH doing to notify healthcare providers of health concerns?

The Massachusetts Department of Public Health's Radiation Control Program (MDPH/RCP) has issued an information notice to medical licensees who are in the practice of administering I-131, advising them of concerns and actions that should be taken to reduce exposure to I-131.

Recommendations in this document include:

Patients who have received therapeutic I-131 treatments should:

- Avoid direct or indirect contact, including shared living space with infants and young children (e.g., consider having children stay outside the home or with other family members) for a specific period of time, in general a few days, but patients should ask their health care provider.
- Have adequate living space at home that can be used only by the patient (e.g., a bedroom) for a specific period of time, in general a few days, but patients should ask their health care provider.
- Understand the potential for increased risk of thyroid cancer in children exposed to therapy patients if the physician's recommendations are not followed.

Hospitals should consider not releasing patients following therapeutic treatment with I-131 if there might be a risk of exposure to children or infants at home.

What other regulatory concerns are associated with patients receiving radiopharmaceutical treatment?

After receiving treatment or diagnosis with radiopharmaceuticals (including, but not limited to, those containing I-131), many patients return home and contaminated items are often thrown out in household trash. While hospitals often instruct patients on how to prevent radioactive contamination from bodily fluids (e.g., saliva, urine and blood), and the materials that could become contaminated from contact with them (e.g., facial tissues, incontinence diapers, sanitary napkins and other disposable materials), patients are not always aware of the impacts that can occur from the improper disposal of these items into regular household trash.

Solid waste materials, such as diapers, tissues or articles of disposable bedding or clothing possibly contaminated with radioactive materials should **not** be disposed of in the regular trash. Instead, these materials should be placed in a heavy plastic garbage bag or sealable container which should then be stored in a secure place away from people (e.g., a closet, remote hallway, entryway or shed) until its radioactive contents have had sufficient time to decay. Your medical provider should give you verbal instructions and written information about how long it will take for the radioactive material to decay, and when the items may be disposed of as regular household trash. Your medical provider may also be able to discuss alternative safe disposal options with you.

THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
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DOCKET INFORMATION

Docket Number 04-4092	Facility: HOTEL
License Number	
Request Received: 4/10/03	Action Type[1] ALLEG No.:
Request Assigned: 4/10/03	Primary Reviewer Assigned: JS
Due Date: 5/10/03	Second Reviewer Assigned:
Ackn. Letter Sent:	Amendment fee required: $

LICENSE REVIEW TRACKING

ACTION	DATE
Reviewer # 1 Finishes Review	John Summers 10/29/03
Reviewer # 2 Finishes Review	
FINAL Review Peformed (by MM)	[signature] 10/29/2003

DOCUMENTATION TRACKING

TYPE OF RESPONSE	DATE
MRCP (deficiency letter, etc.) (#1)	
Response to Deficiency Letter (#1)	
MRCP (deficiency letter, etc.) (#2)	
Response to Deficiency Letter (#2)	
MRCP (deficiency letter, etc.) (#3)	
Response to Deficiency Letter (#3)	
Action completed (Docket No. closed)	10/30/2003

1 - ACTION TYPES

ALLEG - Allegation
AMEND - Amendment
EVENT - Licensee Incident
FINAS - Financial Assurance
LICCR - License Correction
NEWLI - New License
RECIP - Reciprocity
RENEW - License Renewal
SSDAM - SSD Registration Amendment
SSDEV - SSD New Reg. Evaluation
SSDIN - SSD Registration Inactivation
TERMI - License Termination
VOIDL - Voided Licensing Action

MEMORANDUM
October 29, 2003

To: File

From: John Sumares

RE: Docket # 04-4092 - Allegation of I-131 Therapy Patient Sent to a Hotel

In April 2003, the Agency received an allegation that a patient who was to receive I-131 therapy was advised to go to a hotel for a few days after treatment. The allegation was submitted by a 'friend' of the patient via e-mail correspondence. The patient was never identified and the details of the treatment were not clearly presented to the Agency. After a few e-mail correspondences with the allegeur, the Agency determined that the treatment was to take place at Beth Israel Deaconess Medical Center.

The Agency contacted the RSO, Rosemary Kennedy, to report this allegation. The RSO stated that releasing an I-131 therapy patient to a hotel is not their normal procedure. The Agency requested a policy statement from BIDMC regarding the release of I-131 therapy patients.

In July 2003, the Agency received from BIDMC a document titled 'Radiation Safety Committee Policy - Iodine-131 Therapy'. This policy statement indicated that BIDMC used numerous criteria to determine the best course for administration of I-131 therapy - ie., outpatient vs. hospitalized treatment. The policy also stated "BIDMC recommends that under no circumstances should an individual undergoing this type of therapy use hotels, motels, or any public accommodations."

The Agency contacted the allegeur by e-mail to report that the Agency had been satisfied with the BIDMC policy statement and to ask the status of her friend's treatment. The allegeur replied that her friend had the treatment in June and did go to a hotel afterwards. The allegeur did not request any further action by the Agency.

In August, the Agency re-contacted the RSO of BIDMC to report this communication and to request the RSO to investigate with all authorized users the details of treatments administered in June. The RSO responded with a letter dated September 19, 2003, in which it stated that all authorized users did not discharge a therapy patient to a hotel, that the radiation safety staff instructed all therapy patients not to go to a hotel or motel following I-131 treatment, and that the patient instruction handout, given to all AU's, includes the following instruction: "Hotels and similar lodgings should not be used."

The Agency considers this matter closed for the following reasons:

The patient, who remains anonymous, has not contacted the Agency.
The allegeur has not asked for further action by the Agency.
The licensee, BIDMC, could not identify the patient and has implemented a means to inform future I-131 therapy patients about NOT using public accommodations after treatment.

Beth Israel Deaconess Medical Center

A major teaching hospital of Harvard Medical School

Radiation Safety Office

John Sumares
Radiation Control Program
Department of Public Health
Executive Office of Health and Human Services
Commonwealth of Massachusetts
90 Washington Street, Dorchester, MA 02121

9/19/2003

Re: Hotel allegation

Dear Mr. Chapel

We have reviewed this allegation with all the authorized users (physicians) who treated I-131 patients in June 2003.

While patients are referred to these authorized users from many physician sources, only authorized users, as approved by our Radiation Safety Committee, treat I-131 patients at BIDMC. I have contacted each of the authorized users who treated patients in June 2003. Each has stated that they did not discharge the patients to hotels or motels following I-131 treatment.

In addition my staff discusses precautions with each patient before they are administrated I-131. My staff has confirmed to me that they instructed each patient in June not to go to a hotel or motel after treatment.

We have now updated our patient instruction handout to include the following instruction: "Hotels and similar lodgings should not be used" All authorized users have been given this up to date instruction handout.

Sincerely

M. Rosemary Kennedy
Radiation Safety Office

330 Brookline Avenue
Boston, MA 02215

(617) 667-2510
fax (617) 667-4320